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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/908,884	08/08/97	DONG	X 00786/33904

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EXAMINER	
NELSON, A	
ART UNIT	PAPER NUMBER
1638	20
DATE MAILED: 08/08/00	

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/908,884

Applicant(s)

Xinnian Dong, et al.

Examiner

Amy Nelson

Group Art Unit

1638



☒ Responsive to communication(s) filed on Jul 28, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 2, 4-13, 15-29, 36, and 40-42 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 4-13, 15-29, 36, and 40-42 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.
2. The amendment filed 7/28/00 has been entered.
3. Finality of the Official action mailed 7/26/99 has been withdrawn in view of the recent availability of a reference, and the resulting new ground of rejection as set forth below.

Claim Rejections - 35 USC § 112

4. Claims 1, 2, 4-13, 15-29, 36, and 40-42 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record set forth in the Official action mailed 12/7/98 and 7/26/99. Applicant's arguments filed 7/28/00 have been fully considered but they are not persuasive.

Applicant asserts that, in view of the disclosure of an ankaryin repeat consensus in Fig. 6, Applicant's invention clearly encompassed not a single gene, but a family of disease resistance

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genes encoding the ankaryin repeat. Applicant argues that the ankaryin repeat is not an insignificant sequence, but comprises at least 20% of the encoded protein. Moreover, Applicant asserts that the family of sequences instantly disclosed can be distinguished from other sequences comprising an ankaryin repeat by their disease resistance properties. By disclosure of structural features common to the genus, Applicant has satisfied the written description requirement (response, p. 6-9). Examiner responds that Applicant has described a single isolated DNA which encodes a polypeptide which demonstrably functions in disease resistance (SEQ ID NO:2, encodes SEQ ID NO:3). Applicant has not described other DNAs related to the isolated DNA, and hence has not described a representative number of species of the claimed genus. Applicant teaches that the disclosed DNA encodes a polypeptide comprising an ankaryin repeat consensus sequence, which mediates protein interaction, and which is found in other functionally unrelated polypeptides, such as a mouse ankyrin protein and a G-protein coupled receptor motif (see Fig. 6). Hence, the ankyrin motif is not a structural feature unique to the claimed genus of sequences involved in disease resistance. Moreover, Applicant has not described another disease resistance polypeptide comprising an ankaryin repeat, and hence it is not clear that a genus of disease resistance polypeptides comprising an ankaryin repeat even exists. Therefore, the instant rejection is maintained.

5. Claims 1, 2, 4-13, 15-29, 36, and 40-42 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to an isolated DNA

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molecule that encodes the polypeptide of SEQ ID NO:14, a vector, transformed host cell, and transgenic plant comprising said DNA molecule, and methods of producing said polypeptide in a host cell, and of providing increased disease resistance in a transgenic plant with said DNA molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record set forth in the Official actions mailed 12/7/98 and 7/26/99. Applicant's arguments filed 7/28/00 have been fully considered but they are not persuasive.

Applicant asserts that the instant specification provides guidance for design of oligonucleotides, low and high stringency hybridization, library screening, and PCR, which would allow isolation of related nucleic acid sequences. Specifically, Applicant teaches isolation of a tobacco DNA by hybridization with the disclosed full length *Arabidopsis NPR1* cDNA, and teaches that the encoded polypeptide comprises an ankyrin repeat consensus sequence. Further, Applicant teaches the presence of a hybridizing band in Northern analysis of potato RNA. Identification of those nucleic acid sequences which encode disease resistance polypeptides could be achieved by screening of plants transformed with the nucleic acid sequences (response, p. 9-12). Examiner responds that Applicant provides only general guidance for isolation of functionally related nucleic acid sequences. Applicant has not provided any evidence that the isolated tobacco DNA encodes a disease resistance polypeptide, and hence it is unclear that the isolated DNA is functionally related to the disclosed *Arabidopsis NPR1* cDNA. Also, Applicant has not isolated a

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structurally and functionally related DNA from potato. Hence, Applicant has not provided specific guidance for isolation of other structurally related nucleic acid sequences which encode disease resistance polypeptides. The basis for doubting that structurally related nucleic acids would necessarily confer disease resistance in plants is that the ankyrin repeat motif has been identified in many different functionally unrelated proteins. Hence, structural relatedness alone is not sufficient basis to predict functional relatedness. Applicant's teaching of screening transformed plants for enhanced disease resistance is merely an invitation to experiment, and does not constitute specific guidance for isolation of structurally and functionally related DNAs to the disclosed *Arabidopsis NPR1* cDNA.

6. Claims 10-13, 15-29, 36, and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reasons of record set forth in the Official action mailed 12/7/98 and 7/26/99. Applicant's arguments filed 7/28/00 have been fully considered but they are not persuasive.

At Claims 10-12, the phrase "specifically hybridizes to" is indefinite. Applicant asserts that the phrase is defined in the specification to mean "hybridizing to a DNA sequence under at least low stringency conditions as described herein, and preferably under high stringency conditions, also as described herein." Applicant further asserts that the specification provides exemplary conditions for both low stringency and for high stringency. Hence, one of skill in the art would be

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reasonably apprised of the scope of the claimed invention (response, p. 13-15). Examiner responds that the scope of the claimed invention would not be clear to one of skill in the art because it is not clear if the claimed invention encompasses nucleic acid molecules which would hybridize at low stringency conditions or those which would hybridize at high stringency conditions. Also, because the specification provides multiple definitions, and/or uses the language "for example" or "may include," Applicant has not provided a clear definition of "low stringency" or of "high stringency." Hence, the metes and bounds of the claimed invention are unclear.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1, 2, 4-13, 15-29, 36, and 40-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Ryals *et al.* (U.S. Patent 6,091,004; EFD=6/21/96).

Ryals discloses an isolated genomic DNA and cDNA from *Arabidopsis* which encodes NIM1, a protein in the SAR signal transduction pathway leading to resistance in plants to a variety of plant pathogens, including fungi, bacteria, viruses and nematodes (col. 2, line 65 - col. 3, line 7; col. 10, line 16 - col. 11, line 13; Examples 9 and 15; SEQ ID NO:2 and 3; ATCC

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Deposit 97543). The encoded amino acid sequence of Ryals is 100% identical to SEQ ID NO:3 of the instant application, and hence comprises an ankaryin repeat. Ryals also teaches isolation of functionally related nucleic acids from other plant species, including members of the plant species *Solanaceae* (col. 11, line 28- col. 12, line 15; Example 17). Ryals teaches construction of vectors comprising the isolated DNA operably linked to a promoter, teaches expression of said vector in *Agrobacterium* and in a variety of plant species, and teaches that the transformed plants have increased PR-1 gene expression and enhanced disease resistance to a variety of pathogenic agents, including *Phytophthora parasitica* (col. 12, line 17 - col. 15, line 5; Examples 10, 18, 21, and 22; Tables 4 and 6). Hence, all of the claim limitations were previously disclosed by Ryals.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the Group receptionist whose telephone number is (703) 308-1234.



AMY J. NELSON, PH.D
PRIMARY EXAMINER

Amy J. Nelson, Ph.D.

August 7, 2000